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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/869,206

Applicant(s)
Czaki

Examiner
Arun Chakrabarti

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 17, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/869,206.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Election of Group I, corresponding to claims 1-24, in paper number 7, is hereby acknowledged. Non-elected claims 25-36 have been canceled without prejudice towards further prosecution.

Specification

2. In claim 3 the phrase "covers" on line 3 is suggested to be changed to "cover".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "capable of" on line 7 of the claim renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

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Claim 17 is rejected over the recitation of the phrase, "enter into coordination compounds". It is not clear how the binding partner molecules are entering into some other compounds. Is it intermolecular entering or intramolecular entering or both? It is also not clear what type of coordination compounds are claimed. Is the chemical coordination claimed or biological coordination claimed or both are claimed. The metes and bounds of the claim are vague and indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 17-18, 20, and 22-24 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yamashita (U.S. Patent 5,646,420) (July 8, 1997).

Yamashita teaches affinity sensor for detecting specific binding events, comprising a carrier substrate provided with at least two electrodes and having a predetermined area, the electrodes being equidistantly spaced apart from each other and engagingly bordering the area from both sides, at least the area being adapted for receiving immobilized specific binding partners, the specific binding partners being capable of coupling complementarily associated binding partners directly or via further specific binding molecules, the area having a minimum width adapted for capture of at least one complementarily associated being partner provided with

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one electrically conductive particle within the area in such a way as to allow for formation of a respective tunnel contact junction between the particle and the electrodes (Abstract, Figure 1, Claims 1 and 11, and Column 1, line 50 to column 3, line 37).

Yamashita teaches affinity sensor, wherein the width is under 800 nm.(Column 1, lines 16-20).

Yamashita teaches affinity sensor for detecting specific molecular binding events, wherein the immobilized specific binding partners cover the electrodes with a thickness which permits tunnel effects (Claims 1 and 11, and Column 1, line 50 to column 3, line 37).

Yamashita teaches affinity sensor for detecting specific molecular binding events, wherein the electrodes are each two micro-electrodes arranged in a pair, the electrodes being connected to an amplifier circuit with an associated measuring and evaluating unit so that an electric current flow across the area can be detected when there is a voltage applied across the electrode (Column 5, lines 1-12).

Yamashita inherently teaches affinity sensor for detecting specific molecular binding events, wherein the electrodes are part of the amplifier circuit and project from out of the latter (Column 5, lines 1-12).

Yamashita inherently teaches affinity sensor for detecting specific molecular binding events, wherein the specific binding partners enter into coordination compounds (Abstract and Column 4, lines 1-49).

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Yamashita teaches affinity sensor for detecting specific molecular binding events, wherein the specific binding partners are bioactive or biomimetic protein molecules (Abstract, Figure 1, Claims 1 and 11, and Column 1, line 50 to column 3, line 37).

Yamashita teaches affinity sensor for detecting specific molecular binding events, wherein the conductive particles are of sizes in the nanometer to micrometer range. (Column 1, lines 16-20).

Yamashita teaches affinity sensor for detecting specific molecular binding events, wherein the conductive particles consist of metal-cluster compounds (Column 2, lines 17-29).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-6, and 16-24 are rejected under 35 U.S.C. 103 (a) over Yamashita (U.S. Patent 5,646,420) (July 8, 1997) in view of Peeters (U.S. Patent 6,325,904 B1) (December 4, 2001).

Yamashita teaches affinity sensor and the amplifier circuit of claims 1-5, 17-18, 20, and 22-24 as described above.

Yamashita do not teach a microchip.

Peeters teaches a microchip (Abstract and Figures 1-7).

Yamashita does not teach the other specific binding partner nucleic acids and saccharides.

Peeters teaches the other specific binding partner nucleic acids and other molecules (Column 3, lines 53-55 and column 4, lines 56-6).

Yamashita does not teach the affinity sensor, wherein a plurality of reference areas is provided being occupied with different inactive binding partner.

Peeters teaches the affinity sensor, wherein a plurality of reference areas is provided being occupied with different inactive binding partner (Figures 1-6).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the microchip and detection of other specific binding partner of Peeters into the affinity sensor of Yamashita, since Peeters states, "Thus, it is an object of the present invention to provide a novel and rapid method to analyze small biological molecules in solutions such as proteins and to sequence DNA by using semiconductor

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chip technology with extremely high packing densities (Column 3, lines 47-51).” By employing scientific reasoning, an ordinary artisan would have combined and substituted the microchip and detection of other specific binding partner of Peeters into the affinity sensor of Yamashita in order to improve the analysis of biological molecules. An ordinary practitioner would have been motivated to combine and substitute the microchip and detection of other specific binding partner of Peeters into the affinity sensor of Yamashita in order to achieve the express advantages noted by Peeters, of an invention which provides a novel and rapid method to analyze small biological molecules in solutions such as proteins and to sequence DNA by using semiconductor chip technology with extremely high packing densities.

9. Claims 1-12, and 14-24 are rejected under 35 U.S.C. 103 (a) over Yamashita (U.S. Patent 5,646,420) (July 8, 1997) in view of Peeters (U.S. Patent 6,325,904 B1) (December 4, 2001) further in view of Oyama et al. (U.S. Patent 5,552,274) (September 3, 1996).

Yamashita in view of Peeters teach affinity sensor and the amplifier circuit of claims 1-6, and 16-24 as described above. Moreover, Peeters teaches affinity sensor wherein the chip surface is formed by a silicon wafer or by a glass target and wherein the affinity areas are separated from each other at their intersections by an insulating layer arranged between the intersections (Figure 5 and Column 8, lines 42-64).

Peeters also teaches affinity sensor, wherein the occupation density of the specific binding patterns on the individual area is different and the individual affinity areas carry different specific binding patterns (Abstract and Figures 1-5).

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Yamashita in view of Peeters do not teach a comb electrode structure, wherein the affinity areas are arranged on a common chip surface.

Oyama et al. teach a comb electrode structure, wherein the affinity areas are arranged on a common chip surface (Column 2, lines 26-32).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the comb electrode structure, wherein the affinity areas are arranged on a common chip surface of Oyama et al. into the affinity sensor of Yamashita in view of Peeters, since Oyama et al. state, "J.C. Andle et al have reported the successful detection of DNA by the use of a sensor comprising a so-called SAW device having a comb electrode formed on the surface of a piezoelectric plate. In this report, the sensitivity of DNA detection is indicated to be 0.1 nanogram in mass sensitivity (Column 2, lines 26-31)." By employing scientific reasoning, an ordinary artisan would have combined and substituted the comb electrode structure, wherein the affinity areas are arranged on a common chip surface of Oyama et al. into the affinity sensor of Yamashita in view of Peeters in order to improve the analysis of biological molecules. An ordinary practitioner would have been motivated to combine and substitute the comb electrode structure, wherein the affinity areas are arranged on a common chip surface of Oyama et al. into the affinity sensor of Yamashita in view of Peeters in order to achieve the express advantages, as noted by Oyama et al., of an invention which provides a successful detection of DNA by the use of a sensor comprising a so-called SAW device having a

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comb electrode formed on the surface of a piezoelectric plate and in which the sensitivity of DNA detection is indicated to be 0.1 nanogram in mass sensitivity.

10. Claims 1-24 are rejected under 35 U.S.C. 103 (a) over Yamashita (U.S. Patent 5,646,420) (July 8, 1997) in view of Peeters (U.S. Patent 6,325,904 B1) (December 4, 2001) further in view of Oyama et al. (U.S. Patent 5,552,274) (September 3, 1996) further in view of Heller et al. (U.S. Patent 6,281,006 B1) (August 28, 2001).

Yamashita in view of Peeters further in view of Oyama et al. teach the affinity sensor of claims 1-12, and 14-24 as described above.

Yamashita in view of Peeters further in view of Oyama et al do not teach the affinity sensor wherein at least one reference area is provided which carries inactive binding partner for a reference measurement instead of the specific binding partners.

Heller et al teach the affinity sensor wherein at least one reference area is provided which carries inactive binding partner for a reference measurement instead of the specific binding partners (Column 5, lines 43-59).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the affinity sensor wherein at least one reference area is provided which carries inactive binding partner for a reference measurement instead of the specific binding partners of Heller et al. into the affinity sensor of Yamashita in view of Peeters further in view of Oyama et al since Heller et al. state, "Preferably the reference electrode is one that does not leach ions and maintains a constant potential (Column 5, lines 54-

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55).” By employing scientific reasoning, an ordinary artisan would have combined and substituted the affinity sensor wherein at least one reference area is provided which carries inactive binding partner for a reference measurement instead of the specific binding partners of Heller et al. into the affinity sensor of Yamashita in view of Peeters further in view of Oyama et al. in order to improve the analysis of biological molecules. An ordinary practitioner would have been motivated to combine and substitute the affinity sensor wherein at least one reference area is provided which carries inactive binding partner for a reference measurement instead of the specific binding partners of Heller et al. into the affinity sensor of Yamashita in view of Peeters further in view of Oyama et al. in order to achieve the express advantages, as noted by Heller et al., of reference electrode that does not leach ions and maintains a constant potential.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Arun K. Chakrabarti

Arun Chakrabarti,

**ARUN K. CHAKRABARTI
PATENT EXAMINER**

Patent Examiner,

February 13, 2002